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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,567	03/23/2001	Fred T. Parker	PA-5245-RFB	6497

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Indiabapolis, IN 46204

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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09/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/815,567

Applicant(s)

PARKER, FRED T.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/23/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 22, the limitation "each coil turn being free of interference from another coil turn" renders the claim vague and indefinite because it isn't clear what Applicant means by "free of interference." Clearly, each turn of the coil of Applicant's invention restricts the movement of adjacent coil turns and thereby interferes with the coil turns.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 9-11, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrigan et al. (US 5,792,124).

Horrigan et al. disclose a catheter or sheath having a unitary lubricous liner or inner tube 40; a reinforcement means or wire braid 35 terminating proximal to the distal end of inner tube 40; a first outer tube 15; a second outer tube 20 wherein the second outer tube 20 is made of softer material than the first outer tube 15 (Figure 3; col. 2, lines 60-67; col. 3, lines 1-20; and col. 8, lines 28-34); and a distal tip 45. Further, Horrigan et al. disclose the use of wire braid 35 to offer better kink resistance (col. 5, lines 1-3). Note that the wire braid has a plurality of wires twisted around a longitudinal

Art Unit: 3733

axis of the sheath. The Examiner is interpreting a single strand of the wire braid to be coil (Fig. 3).

Regarding claims 10-11, Horrigan et al. further disclose a second outer tube 20 made of a material having a hardness range of Shore durometer 25D to 40D and a first outer tube 40 having a hardness range of Shore durometer 50D to 60D. It is noted that a specific example in the prior art, which is within a claimed range, anticipates the range. MPEP 2131.03.

Regarding claim 19, Horrigan et al. disclose that wire braid 35 should not extend more than 1/3 the length of the second outer tube 20 to provide optimum flexibility of tip 45 (col. 5, lines 1-9) or approximately 3 mm or "about 5 mm" (col. 5, lines 16-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Parker (US 5,380,304).

Although Horrigan et al. do not disclose a roughened surface, attention is directed to the Parker reference, which teaches an inner tube 22 having an outer rough surface; a wire coil 23; and an outer tube 12 wherein the outer tube 12 is mechanically connected or bonded to the inner tube 22 and the wire coil by the well-known heat shrinking and formation process (col. 3, lines 67-68 and col. 4, lines 1-3).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the sheath of Horrigan et al. by roughening the outer surface of inner tube 22, as taught by Parker, in order to improve bonding between the outer tube 12, the wire coil 23 and the inner tube 22.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Ju et al (US 5,599,325).

Horrigan et al. do not disclose a sheath wherein the second outer tube 20 of the sheath contains radiopaque filler in the claimed ranges.

Ju et al. teach a sheath 10 wherein the distal end portion of the stem member 34 is a soft tip member 40 made from a polymer and radiopaque filler blend (col. 6, lines 6-14).

Regarding claim 7, Ju et al. teach an outer layer of sheath 10 to contain 0 to 42 percent by weight of radiopaque filler, which is the claimed range of about 20% to 85%.

Regarding claim 8, Ju et al. teach a sheath 10 with a second outer tube containing 0 to 42 percent by weight of radiopaque filler, which is "about 80%" as claimed.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a second outer tube 20 in the sheath of Horrigan et al. wherein the second outer tube 20 is made from a blend of polymer and radiopaque filler as taught by Ju et al. in order to allow viewing of the position of the sheath in the human body.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124).

Horrigan et al. disclose all elements of the claimed invention except for the claimed range of durometer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a durometer in the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of MacDonald et al (US 6,210,396).

Horrigan et al. do not disclose a sheath wherein the first outer tube 15 and the second outer tube 20 are of different colors or shades.

MacDonald et al. teach a catheter body or sheath 15 having a sleeve 120, a distal catheter shaft 35, a radiopaque band 140 and a distal soft tip 40 wherein the color of the sleeve 120 is different from the color of the distal catheter shaft 35, the color of the radiopaque band 140 and the color of the distal soft tip 40 for identification purposes (col. 10, lines 57-62).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided different colors to the first outer tube 15 and the second outer tube 20 in the sheath of Horrigan et al. as taught by MacDonald in order to enable a user to identify the first and the second tubes.

Claims 5 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187).

Horrigan et al. disclose all elements of the claimed except for: (1) a flat wire coil as reinforcement; and (2) an arcuate distal tip having the claimed features.

Park et al. teach a catheter section or sheath with a braided wire coil (Figure 7) for better kink resistance (col. 2, lines 40-43; col. 13, lines 64-67; and col. 14, lines 1-26). Further, Park et al. teach the importance of designing the sheath to enable its manipulation through increasingly small blood vessels (col. 1, lines 30-52).

Regarding claim 5, Park et al., disclose a radiopaque marker band 120 in the distal region of a catheter or sheath 114 to allow viewing of the position of the distal most portion of the sheath 114 (col. 9, lines 25-33). Regarding claim 15, Park et al. teach a wire coil 232 made of one or more ribbons or "flat wire" (Figure 7 and col. 14, lines 15-17).

Regarding claim 16, Park et al. teach a sheath 110 having an arcuate distal tip region 112 to prevent damage to tissue (Figure 2 and col. 9, lines 21-24).

Regarding claim 17, Park et al. teach a sheath 110 having an arcuate distal tip region 112 with a typical length of 2.5 cm to 30 cm (col. 9, line 40).

Regarding claim 18, Park et al. teach a sheath 110 having an arcuate distal tip region 112 that is a quadrant of a circle (Figure 2 and col. 9, lines 21-24).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan et al. with a braided wire coil as disclosed by Park et al. to have facilitated the manufacture of the catheter or sheath with a diameter suitable for application in an environment of increasingly small diameters.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radiopaque marker band 120 as taught by Park et al. in the second outer tube 20 of the Horrigan et al. device for viewing the position of the distal tip 45 of the Horrigan et al. device.

Using an alternate interpretation, claims 1-2, 4-5, 10-13, 15-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187).

Regarding claim 1, Horrigan et al. disclose a catheter or sheath having a unitary lubricous liner or inner tube 40; a reinforcement means or wire braid 35 terminating proximal to the distal end of inner tube 40; a first outer tube 15; a second outer tube 20 wherein the second outer tube 20 is made of softer material than the first outer tube 15 (Figure 3; col. 2, lines 60-67; col. 3, lines 1-20; and col. 8, lines 28-34); and a distal tip 45. Further, Horrigan et al. teach the use of wire braid 35 to offer better kink resistance (col. 5, lines 1-3).

Horrigan et al. do not disclose the use of a flat wire coil, a round wire coil or a braided wire coil as a reinforcement means.

Park et al. teach a catheter section or sheath with equivalent forms of stiffening members or reinforcement for kink resistance, i.e., a flat wire coil, a round wire coil and a braided wire coil (col. 2, lines 40-43; col. 13, lines 64-67; col. 14, lines 1-26; and Figs.

7-9). Further, Park et al. teach the importance of designing the sheath to enable its manipulation through increasingly small blood vessels (col. 1, lines 30-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan et al. with a braided wire coil, a flat wire coil or a round wire coil as disclosed by Park et al. to have facilitated the manufacture of the catheter or sheath with a diameter suitable for application in an environment of increasingly small diameters.

Regarding claim 2, Horrigan et al. disclose that the materials of the outer jacket of the sheath including the inner tube 40, wire braid 35, first outer tube 15 and second outer tube 20 are bonded (col. 5, lines 47-56).

Regarding claim 4, Horrigan et al. further disclose that the inner tube 40; the wire braid 35; the first outer tube 15 and the second outer tube 20 are fused or bonded by heating (col. 5, lines 47-56).

Regarding claim 5, although the Horrigan et al. device does not include a radiopaque marker band, attention is again directed to Park et al., which disclose a radiopaque marker band 120 in the distal region of a catheter or sheath 114 to allow viewing of the position of the distal most portion of the sheath 114 (col. 9, lines 25-33). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radiopaque marker band 120 as taught by Park et al. in the second outer tube 20 of the Horrigan et al. device for viewing the position of the distal tip 45 of the Horrigan et al. device.

Regarding claims 10-13, Horrigan et al. further disclose a second outer tube 20 made of a material having a hardness range of Shore durometer 25D to 40D and a first outer tube 40 having a hardness range of Shore durometer 50D to 60D.

Regarding claim 15, Park et al. teach a wire coil 232 made of one or more ribbons or "flat wire" (Figure 7 and col. 14, lines 15-17).

Regarding claim 16, Park et al. teach a sheath 110 having an arcuate distal tip region 112 (Figure 2 and col. 9, lines 21-24).

Regarding claim 17, Park et al. teach a sheath 110 having an arcuate distal tip region 112 with a typical length of 2.5 cm to 30 cm (col. 9, line 40).

Regarding claim 18, Park et al. teach a sheath 110 having an arcuate distal tip region 112 that is a quadrant of a circle (Figure 2 and col. 9, lines 21-24).

Regarding claim 19, Horrigan et al. disclose that the wire braid 35 should not extend more than 1/3 the length of the second outer tube 20 to provide optimum flexibility of tip 45 (col. 5, lines 1-9) or approximately 3 mm (col. 5, lines 16-20).

Regarding claim 20, Horrigan et al. disclose a sheath having a unitary lubricous liner or inner tube 40.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of Parker (US 5,380,304).

Although Horrigan et al. do not disclose a roughened surface, attention is directed to the Parker reference, which teaches an inner tube 22 having an outer rough surface; a wire coil 23; and an outer tube 12 wherein the outer tube 12 is mechanically connected or bonded to the inner tube 22 and the wire coil by the well-known heat shrinking and formation process (col. 3, lines 67-68 and col. 4, lines 1-3).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the sheath of Horrigan et al. by roughening the outer surface of inner tube 22, as taught by Parker, in order to improve bonding between the outer tube 12, the wire coil 23 and the inner tube 22.

Claims 6-9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al., further in view of Ju et al (US 5,599,325).

Regarding claim 6, Horrigan et al. do not disclose a sheath wherein the second outer tube 20 of the sheath contains radiopaque filler.

Ju et al. teach a sheath 10 wherein the distal end portion of the stem member 34 is a soft tip member 40 made from a polymer and radiopaque filler blend (col. 6, lines 6-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a second outer tube 20 in the sheath of

Horrigan et al. wherein the second outer tube 20 is made from a blend of polymer and radiopaque filler as taught by Ju et al. in order to allow viewing of the position of the sheath in the human body.

Regarding claim 7, Ju et al. further disclose a sheath 10 with an outer layer containing 0 to 42 percent by weight of radiopaque filler, which is the claimed range of about 20% to 85%.

Regarding claim 8, Ju et al. disclose a sheath 10 with a second outer tube containing 0 to 42 percent by weight of radiopaque filler, which is "about 80%" as claimed.

Regarding claim 9, Ju et al. further disclose a sheath 10 with a first outer tube containing 0 percent by weight of radiopaque filler, which is substantially free of radiopaque filler.

Regarding claim 21, see the discussion for claims 1, 6, 10, 15, 17 and 19.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of MacDonald et al (US 6,210,396).

Horrigan et al. do not disclose a sheath wherein the first outer tube 15 and the second outer tube 20 are of different colors or shades.

MacDonald et al. teach a catheter body or sheath 15 having a sleeve 120, a distal catheter shaft 35, a radiopaque band 140 and a distal soft tip 40 wherein the color of the sleeve 120 is different from the color of the distal catheter shaft 35, the color of the radiopaque band 140 and the color of the distal soft tip 40 for identification purposes (col. 10, lines 57-62).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided different colors to the first outer tube 15 and the second outer tube 20 in the sheath of Horrigan et al. as taught by MacDonald in order to enable a user to identify the first and the second tubes.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on April 24, 2007 have been fully considered but are not persuasive for the following reasons.

With regard to the rejections of claims 1-2, 4, 9-11, 19 and 20 under 35 USC 102(b) as being anticipated by Horrigan, Applicant's arguments are not persuasive for the following reasons.

On page 8 of REMARKS, Applicant argues that a true coiled reinforcement is structured in a manner such that the spacing between turns is uniform. Applicant's arguments are not directed to claim limitations since claim 1 does not recite that the spacing between the turns is uniform. It is noted that during examination, claims must be interpreted as broadly as their terms reasonably allow. This means that the words of a claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Accordingly, the Examiner is interpreting a coil to be a single ring or spiral within a series of rings or spirals (Source: *Random House Unabridged Dictionary*, © Random House, Inc. 2006.)

With respect to Applicant's arguments that there is no identity of invention between the cited reference and the claim at issue, it is noted that the use of the transitional phrase "comprising" does not rule out the presence of other elements.

The Affidavit submitted by Mr. Sathya Kaliyamoorthy does not state what hardness of PEBAX[®] was used in the FEA analysis. Declarations comparing applicant's invention/results thereof with those of the prior art must relate to the reference relied upon and the comparison must be with disclosure identical with that of the reference. Where the comparison is not identical with the reference disclosure, deviations should be explained or should be noted and evaluated.

The Examiner has considered the Affidavit submitted by Mr. Brett O. Baker. However, the declaration has no probative value since it appears to be an expression

Art Unit: 3733

of an opinion by an expert in the art. Declarations must set forth facts, not mere conclusions and the facts presented must be pertinent to the rejection.

Applicant's arguments on page 15 that "Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a braid, and provides no reasons why one skilled in the art would use a coil" it is noted that kink resistance is not an issue in the claim.

Park et al. teach the substitution of coils for braids (Figs. 7-9) and demonstrate the equivalence of one known type of reinforcement, for e.g. braid, for another, for e.g. coil, to yield predictable results, i.e., controlling the flexibility of an intravascular device, thereby rendering the claimed invention obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

September 4, 2007

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